Attachment 14

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA's Response to External Peer Review of Quantitative Consumer Research on Cigarette Health Warnings Required by the Family Smoking Prevention and Tobacco Control Act (Experimental Study on Warning Statements for Cigarette Graphic Health Warnings and Experimental Study of Cigarette Warnings), February 4, 2020

I. INTRODUCTION

To fulfill its statutory obligation under Section 201 of the Tobacco Control Act (TCA) (Pub. L. 111-31), Food and Drug Administration (FDA) has developed, refined, and tested new cigarette health warnings that depict the negative health consequences of cigarette smoking. Pursuant to Section 202(b) of the TCA, the Secretary may, through a rulemaking, adjust the text of the label requirements if doing so would "promote greater public understanding of the risks associated with the use of tobacco products." As part of the cigarette health warning development process, FDA developed new textual warning statements that were tested in a quantitative consumer research study (Study 1). Based on the results of Study 1, FDA selected warning statements that were then paired with concordant photorealistic images that depicted the negative health consequences of cigarette smoking to form cigarette health warnings; those warnings were tested in a second study (Study 2).

Versar, Inc., an independent contractor, coordinated an external letter peer review of these two quantitative consumer research studies on cigarette health warnings. The peer review was conducted for FDA's Center for Tobacco Products. For this peer review, six experts were selected by Versar, Inc. to evaluate and provide written comments on the format and content of the reports from these two studies, including both the clarity of the documents, the presentation of the studies, and the scientific content of the studies.

In Section II of this peer review response report, we list the charge questions given to the reviewers regarding the objective of the peer review and specific advice sought through the peer review. In Section III of this peer review response report, we provide a summary of the peer reviewers' comments followed by either a description of any changes made to the study reports in response to peer reviewer comments or an explanation of our decision to not make suggested changes. For comments[1] that came up in response to multiple charge questions, we have responded to that feedback in the most relevant charge question and indicate that the feedback was raised in elsewhere. The individual peer reviewer comments are provided in tabular format in Appendix I.

[1] At times, peer reviewers provided comments related to a specific charge question in response to a different charge question, meaning that similar content was included in response to multiple charge questions.

6. Are the outcomes measured appropriate given the study's purpose?

Summary of Comments:
Reviewers noted that the measures used are appropriate; some provided suggestions for other measures that could have also been included in Study 1; and one asked if two outcomes were collinear (i.e., essentially measuring the same underlying construct) and, if so, suggested that one outcome should be dropped. Some reviewers noted that additional details on a theoretical framework or model to better understand how the measures relate to the study's purpose would be helpful, and requested that one be included. One reviewer suggested that such a model was needed to link this study to behavioral outcomes. Reviewers also asked that additional details about the selection and validity of the measures used be added to the report and requested clarification of whether all participants were asked the same set of health belief questions.

FDA Response:
Details about the design of the study, including an explanation of the theory that informed the selection of health belief items evaluated has been added to Section 2.3 of the Study 1 Report. The sources of the health belief items used in the study are now included in Section 2.3 (Instrument Development) and Section 4.1 (Measures and Coding). As one reviewer correctly noted in their comments, behavioral outcomes are outside the scope of the study and therefore are not included in the study. Therefore, we decline to include behavioral outcomes in response to another reviewer's suggestion to the Study 1 Report. Although we appreciate the suggestion of additional items that could have been used, many of the suggested items are not consistent with the narrowly focused purpose of this study or are already addressed by other questions already included in the study. Furthermore, Study 1 is complete, and we are unable to include new measures in this study. Importantly, these suggestions for additional measures to be included do not diminish the usefulness of the measures that were used in the study. With respect to the two potentially overlapping outcomes, since both are included in the Statistical Analysis Plan, we do not support dropping either from the study report for two reasons: 1) for the sake of transparency in the analysis; and, 2) we do not agree that these are the same construct, although we might expect these outcomes to be correlated.

7. Are the study participants included appropriate given the study's purpose?

Summary of Comments:
Overall, the reviewers noted that the sample and sub-groups included in the study were appropriate. Some reviewers asked for more clarification about whether the data were weighted, whereas others recognized that the sample, albeit large and diverse, was a convenience sample. Some reviewers asked for more details on: the smoking status of participants to further analyze the results by sub-group; the variable used to screen participants (i.e., susceptibility); an explanation for excluding adult non-smokers or adult "ever smokers who are susceptible."

FDA Response:
As stated in the Study 1 Report, the sample is a large and heterogeneous convenience sample. Weighting was not performed, and, as explained in the report, the inclusion of different age and smoking-status subgroups was not designed to make the study nationally representative or with the intent to perform sub-group analysis. Rather, as now explained in more detail in Section 2.2 (Sampling Frame and Sampling Methodology) the intent was to obtain a large and heterogeneous sample to test

(Experimental Design) and added three examples of the warnings displayed on the mock pack in Appendix A (Study Stimuli). As for the decisions made for inclusion of specific warnings in this study, we note that those decisions were informed in part by the results of Study 1, which we now explain in the Executive Summary.

6. Are the outcomes measured appropriate given the study's purpose?

Summary of Comments:
Three reviewers noted that the measures used were appropriate, and some also provided suggestions for other measures that could have also been included in Study 2. Some reviewers noted that a theoretical framework or model to better understand how the measures relate to the study's purpose was not included in the report and requested that a framework/model be included. Reviewers also asked that more details about the selection and validity of the measures used be added to the report. Additionally, some reviewers requested clarification about participants' interpretation of item B1 ("Before today, had you heard about the specific smoking-related health effect described in the warning"), suggested that additional analyses should have been conducted to rule out a general halo effect (the effect of exposure to a warnings on one topic having an effect on outcomes for a similar, but unrelated topic), and asked questions about how the relative lower levels of perceived factuality may translate into acceptance of the warnings once implemented.

FDA Response:
Details about the design of Study 2, including the theories that informed the selection of questions used, has been added to Section 2.3 (Instrument Development). The source of the items used is now noted both in Section 2.3 (Instrument Development) and Section 4.1 (Measures and Coding). The item "Before today, had you heard about the specific smoking-related health effect described in the warning" (B1) was asked once for each cigarette health warning; the intent of this item, as the reviewer noted, was to assess if the information about any of the health effects included in each warning was new information to participants, as now further explained in Section 4.1 (Measures and Coding). Participants in this study were only exposed to one warning (with a single warning statement) and outcomes focused on the content of that warning. Thus, although the study included multiple treatment conditions, with participants in each exposed to a different warning, the main focus of the analysis was on the effect of each individual warning on outcomes related to that warning. Even if there were a halo effect on beliefs other than those directly related to the warning participants were exposed to, such a finding would not diminish the findings of the study for that warning. We note that the inverse association between the "novelty" of a health warning and its believability/perceived factuality is a common finding in pre-implementation studies (e.g., Hammond Fong 2006; Kennedy 2012; Hammond 2011). Importantly, such findings in pre-implementation studies do not suggest that the warnings will not have the intended effects. We also note, as described in the Study 2 Report, that the absolute level of perceived factuality was very high for all cigarette health warnings tested, even though many of the health conditions included in them were on novel topics.

7. Are the study participants included appropriate given the study's purpose?

Summary of Comments:
Overall, reviewers commented that the study participants were appropriate to address the research